MAY 31 2001

K010865

510(k) SUMMARY

Submitter Information.
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Date Summary Prepared: May 23, 2001

Introduction
The Amsco Century Medium Steam Sterilizer is a Class II medical device as defined by 21 CFR §880.6880. The Amsco Century Medium Steam Sterilizer is substantially equivalent to the predicate devices, the Millennium Steam Sterilizer, K000077 and Amsco Century Steam Sterilizer K964332.
The Amsco Century Medium Steam Sterilizer is intended for the terminal sterilization of heat and moisture-stable materials in healthcare facilities.

The Amsco Century Medium *Prevacuum* Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-A):

Table 1-A

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
PREVAC	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
PREVAC	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
GRAVITY	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
LIQUID	250°F (121°C)	45 minutes	0 minutes	*Refer to Table 3 for guidelines.*

The Amsco Century Medium *Steam Flush Pressure-Pulse (SFPP)* Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-B):

Table 1-B

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
WRAP /SFPP	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Non-Porous Goods only. *Refer to Table 2 for recommended quantities.*
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
PREVAC	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table*

	(132°C)			*2 for recommended quantities.*
GRAVITY	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*

The following table (Table 2) is STERIS's recommended loads by sterilizer size:

Table 2

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26x37.5x36" (660x950x910mm)	9	18
26x37.5x48" (660x950x1220mm)	12	30
26x37.5x60" (660x950x1520mm)	15	36

The following table (Table 3) are the liquid cycle processing guidelines:

Table 3

Number of Containers	Volume of Liquid in One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
3	1000 ml	45 minutes

Effectiveness

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} reduction. STERIS validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, the Amsco Century Medium Steam Sterilizer will be validated to meet the requirements of AAMI/ANSI-ST8, Third Edition, January 1994.

The results of the Amsco Century Medium Steam Sterilizer verification studies demonstrate that the sterilizer performs as intended and are summarized as follows:

- All SFPP cycles verified using the fabric test pack, as described in Section 5.5.1.1 of AAMI/ANSI-ST8, were qualified according to Section 5.5.1 AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All SFPP cycles verified using full load instrument trays were qualified according to Section 5.5.3 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} by ½ cycle analysis, a moisture retention of less than 20% increase in the presterilization weight of the towel, and exhibited no wet spots on the outer wrapper.
- All GRAVITY cycles verified using the fabric test pack, as described in Section 5.5.1.1 of AAMI/ANSI-ST8, were qualified according to Section 5.5.1 AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All PREVAC cycles verified using the fabric test pack, as described in Section 5.5.1.1 of AAMI/ANSI-ST8, were qualified according to Section 5.5.1 AAMI/ANSI-ST8. These cycles

demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.

- All PREVAC cycles verified using full load instrument trays were qualified according to Section 5.5.3 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} by ½ cycle analysis, a moisture retention of less than 20% increase in the presterilization weight of the towel, and exhibited no wet spots on the outer wrapper.
- All LIQUID cycles verified using three 1,000 ml flasks, as described in Section 5.5.2.1 of AAMI/ANSI-ST8, were qualified according to Section 5.5.2 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a water loss not exceeding 50 ml, and automatic sealing of the flask closure.
- The DART cycle was verified using the Bowie-Dick Test Pack were qualified according to Section 5.6 of AAMI/ANSI-ST8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (5/29/98)*".

Safety

STERIS sterilizers including the Amsco Century Medium Steam Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco Century Medium Steam Sterilizer will comply with the following requirements:

- Underwriters Laboratory (UL) Electromedical Code 3101 as certified by ETL Testing Laboratories, Inc.
- Canadian Standards Association (CSA) Standard C22.2 No. 1010-1
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels

Hazards-Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incidence of sterilizer malfunction or sterilization process failure is relatively rare considering the widespread use of steam sterilizers. Further, there are no known reports in the literature of patient infections that have resulted from steam sterilizer failure. The technology designed in STERIS steam sterilizers including the Amsco Century Medium Steam Sterilizer provides microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User Information

STERIS conducts in-house user training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator's Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Mr. Raymond Ursick
Vice President of RA/QS
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K010865
Trade/Device Name: Amsco Century Medium Sterilizer
Regulation Number: 880.6880
Regulatory Class: II
Product Code: FLE
Dated: March 21, 2001
Received: March 22, 2001

Dear Mr. Ursick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010865

INDICATIONS FOR USE STATEMENT
DEVICE NAME: AMSCO CENTURY MEDIUM STERILIZER

INDICATIONS FOR USE:

The Amsco Century Medium Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities and available in two medium size models:

- *Prevacuum* - designed for sterilization of heat and moisture-stable materials. The Prevacuum sterilizer is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* - designed for sterilization of heat and moisture-stable materials. The SFPP sterilizer is equipped with SFPP, WRAP/SFPP, Prevacuum, Gravity, Leak Test, and DART (Bowie-Dick) cycles.

The Amsco Century Medium *Prevacuum* Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-A):

Table 1-A

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
PREVAC	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
PREVAC	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
GRAVITY	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
LIQUID	250°F (121°C)	45 minutes	0 minutes	*Refer to Table 3 for guidelines.*

The Amsco Century Medium *Steam Flush Pressure-Pulse (SFPP)* Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-B):

Table 1-B

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
WRAP/SFPP	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Non-Porous Goods only. *Refer to Table 2 for recommended quantities.*
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
PREVAC	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
GRAVITY	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*

The following table (Table 2) is STERIS's recommended loads by sterilizer size:

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Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26x37.5x36" (660x950x910mm)	9	18
26x37.5x48" (660x950x1220mm)	12	30
26x37.5x60" (660x950x1520mm)	15	36

The following table (Table 3) are the liquid cycle processing guidelines:

Table 3

Number of Containers	Volume of Liquid in One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
3	1000 ml	45 minutes

The Amsco Century Medium Steam Sterilizer is offered in the following medium-sized configurations:

Hinged Door Configurations:

- 26x37.5x36" (660x950x910mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x36" (660x950x910mm) Single Door, SFPP and Double Door, Prevacuum
- 26x37.5x48" (660x950x1220mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x48" (660x950x1220mm) Single Door, SFPP and Double Door, SFPP
- 26x37.5x60" (660x950x1520mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x60" (660x950x1520mm) Single Door, SFPP and Double Door, SFPP

Horizontal-Sliding Door Configurations:

- 26x37.5x36" (660x950x910mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x36" (660x950x910mm) Single Door, SFPP and Double Door, SFPP
- 26x37.5x48" (660x950x1220mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x48" (660x950x1220mm) Single Door, SFPP and Double Door, SFPP
- 26x37.5x60" (660x950x1520mm) Single Door, Prevacuum and Double Door, Prevacuum
- 26x37.5x60" (660x950x1520mm) Single Door, SFPP and Double Door, SFPP

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010865